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LAW DEPARTMENT
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SEATTLE, WA 98119

In re Application of:
Manfred Brockhaus et al.
Serial No.: 08/444,790
Filed: May 19, 1995
Attorney Docket No.: 9189

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: PETITION DECISION
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This is in response to the petition filed under 37 CFR § 1.181 on August 28, 2008, requesting that the Director acknowledge the alleged new ground of rejection instituted in the Examiner's Answer mailed August 14, 2008. Petitioner requests correction of the Examiner's Answer by identifying the alleged new ground of rejection made by the examiner of record therein and approval of such new ground by the Director of TC 1600.

DISCUSSION

The petition and the file history have been carefully considered.

Petitioner argues that the Examiner's Answer mailed on August 14, 2008 contained new grounds of rejection which were not appropriately identified by the examiner. Petitioner presents two alleged instances of new grounds of rejection apparently raised by the examiner in said Examiner's Answer.

Petitioner's first allegation pertaining to a new ground of rejection focuses on the contention that the examiner instituted a new ground of rejection upon substantively considering petitioner's evidence regarding unexpected results for the first time in the Examiner's Answer:

In the Examiner's Answer mailed on August 14, 2008, Appellants' evidence regarding unexpected results was substantively considered for the first time. The Examiner's Answer admits that most of Appellants' evidence constitutes unexpected results. For example, the Examiner did not dispute that the drastically reduced effector function (pages 64-65), the failure to form aggregating complexes (page 65), the increase in TNF neutralizing potency (page 66), the increased kinetic stability (page 67) and the improved inhibition of TNF (page 67) were each unexpected results. Furthermore, the Examiner's Answer acknowledged that unexpected results sufficient to rebut obviousness could consist of unexpected results for a single member

of a claimed subgenus or for a narrow portion of a claimed range. (Page 63) However, the Examiner's Answer newly alleged that "the skilled artisan could not ascertain a trend in the exemplified data that would allow him to reasonably extend the probative value thereof." (Page 64) The Examiner's Answer also newly stated that "Appellants do not provide any evidence that the unexpected results extend to the full range of the claimed genus of 'soluble fragments' of part (a) of each claim, including mutated variants of a 75 kD insoluble TNF receptor." (Page 64)

MPEP 1207.03 states (in-part)

There is no new ground of rejection when the basic thrust of the rejection remains the same such that an appellant has been given a fair opportunity to react to the rejection. See *In re Kronig*, 539 F.2d 1300, 1302-03, 190 USPQ 425, 426-27 (CCPA 1976). Where the statutory basis for the rejection remains the same, and the evidence relied upon in support of the rejection remains the same, a change in the discussion of, or rationale in support of, the rejection does not necessarily constitute a new ground of rejection. *Id.* at 1303, 190 USPQ at 427 (reliance upon fewer references in affirming a rejection under 35 U.S.C. 103 does not constitute a new ground of rejection). (emphasis added)

However, to reiterate from the final Office action, the examiner disputed the arguments that the showing of unexpected results obviated the outstanding rejection under 35 U.S.C. 103(a) by stating, "Applicants' putative unexpected results appear to be generated using a fusion protein comprising the full-length extracellular domain of the insoluble 75 kD TNF binding receptor and portions of an immunoglobulin molecule....the specification does not provide a description of this particular species of fusion protein. There is no conception...the evidence of unexpected results...is not sufficient to overcome the obviousness of combining the teachings of Dembic in view of Capon." Contrary to petitioner's assertions, this explanation given by the examiner was a sufficient, substantive response to the allegation that the demonstration of unexpected results was adequate to overcome the rejection under 35 U.S.C. 103(a). The examiner's statements "the skilled artisan could not ascertain a trend in the exemplified data that would allow him to reasonably extend the probative value thereof" as well as "Appellants do not provide any evidence that the unexpected results extend to the full range of the claimed genus of 'soluble fragments' of part (a) of each claim, including mutated variants of a 75 kD insoluble TNF receptor" made in the Examiner's Answer were merely supporting the examiner's initial finding that petitioner's unexpected results were not accepted as being commensurate in scope with the breadth of the claimed invention considering that petitioner's data provided to substantiate such an unexpected result only included data with regard to a fusion protein comprising the full-length extracellular domain of the 75 kD TNF receptor and portions of an immunoglobulin molecule. These statements by the examiner are not a new rejection; rather, these statements are merely ancillary to the examiner's original assessment of appellants' assertions of unexpected results and moreover, these statements are in response to appellants' lengthy rebuttal to this issue raised for the first time in the Appeal Brief. Hence, according to the MPEP, statements by the examiner which tend to support or solidify a rejection previously instituted do not constitute a new ground of rejection and petitioner's arguments concerning this issue are not found persuasive.

Additionally, while petitioner provides *In re DeBlauwe* (FED. Cir. 1984) in support of their contentions on this matter, *In re DeBlauwe* is not deemed relevant in the instant case because contrary to petitioner's assertions, the examiner did provide ample reasons in the prosecution

history of this case with regard to petitioner's demonstration of unexpected results in the final Office action. Thus, this does not constitute a new ground of rejection.

The second issue raised by petitioner concerns the examiner's articulation, for the first time in the Examiner's Answer, that monomeric fusion proteins missing a hinge domain made the claimed invention obvious:

Moreover, the Examiner's Answer newly asserted that the claim language "all of the domains of the constant region of an IgG heavy chain other than CH1" included immunoglobulin fragments lacking a hinge domain, and stated for the first time that the claims were interpreted to encompass monomeric fusion proteins missing the hinge. As a result, the Examiner's Answer relied for the first time on the theory that a prior art teaching of monomeric fusion proteins missing a hinge domain rendered obvious Appellants' claims. (See page 61). Furthermore, the Examiner's Answer cited to portions of Capon (cols. 7, 10 and 17) that had not been cited previously, and asserted a different teaching and motivation than explained previously. (See pages 61-62). In the Office Action mailed April 3, 2006, the Examiner referred to the following portions of Capon: col. 22, lines 5-6; col. 26, lines 24-26; col. 29, line 37; col. 30, lines 26-27; col. 31, lines 4-8 and Example 4 (starting at col. 40). (See page 11 of Action) In the Final Action, the Examiner cited the identical portions of Capon. However, in the Examiner's Answer, the following new portions of Capon were cited: col. 10, lines 10-12, col. 10, lines 27-28, col. 10, line 61, col. 17, lines 54-56, and col. 7, lines 13-16. (See pages 14-15 of Final Action). Thus, citations to cols. 7, 10 and 17 of Capon are conspicuously absent from the portions of Capon cited in the previous office actions (pp. 5-6, Petition)

Specifically, the examiner states on page 61 of the Examiner's Answer:

Third, even if the skilled artisan would have predicted a dimeric TNFR-immunoglobulin dimeric to not be able to bind, **the teachings of Capon provide an additional motivation to combine the teachings of Dembic in view of Capon- to construct a monomeric version of the fusion protein encompassed by the claims.** Appellants argue that the claimed protein is 'dimeric', yet this limitation is not recited in the claims or even taught by the specification. Instead, as set forth above, the recitation of 'all of the domains of the constant region of an IgG heavy chain other than CH1' broadly encompasses sequences that contain just the CH2 and CH3 domains and thus encompass fusion proteins in which all, none or a portion of the 'hinge' is present (emphasis added)

The examiner then proceeded from page 61 of the Examiner's Answer to cite passages of Capon to support the motivation to construct a monomeric version of fusion protein which had not previously been cited by the examiner.

Petitioner correctly states that any new ground of rejection made by an examiner in an answer must be prominently identified as a new ground of rejection (MPEP § 1207.02 and 1207.03) (p. 6, Petition).

Petitioner's points on this second issue are well-taken. A detailed review of the Office actions in this case as well as the comments made by the examiner in the Advisory Action reveals that the new motivation as set forth by the examiner on page 61 of the Examiner's Answer is the first instance this motivation was set forth in the prosecution of this case. Thus, by proposing a new motivation for combining the Dembic and Capon references, the examiner did indeed introduce a new ground of rejection.

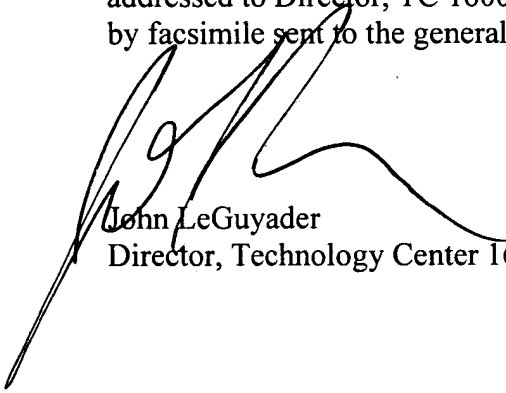
DECISION

The petition is **GRANTED**.

Because the examiner set forth a new ground of rejection in the Examiner's Answer and because the examiner did not properly adhere to the requirements for setting forth a new ground of rejection in the Examiner's Answer by having the Examiner's Answer approved by a Technology Center Director or designee, by specifically recognizing and thus identifying the new ground of rejection in the Examiner's Answer and by providing applicants a two-month time period for reply, the Examiner's Answer was improper and is hereby VACATED.

This application will be forwarded to the examiner to either issue a corrected Examiner's Answer adhering to the provisions set forth in MPEP § 1207.03 I for introducing a new ground of rejection in an Examiner's Answer, by issuing a corrected Examiner's Answer omitting the new ground of rejection identified herein or alternatively, to reopen prosecution to set forth said new ground of rejection.

Should there be any questions about this decision please contact Marianne C. Seidel, by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0584 or by facsimile sent to the general Office facsimile number, 703-872-9306.



John LeGuyader
Director, Technology Center 1600